

Remarks/Arguments

Reconsideration of the above-identified application in view of the present amendment is respectfully requested.

By the present amendment claims 8, 20-36, 38, and 52 are cancelled, claims 1, 16, 37, 40, 43, 44, 46, and 53 are amended, and new claims 55-71 are added. Hence, claims 1-7 , 9-19, 37, 39-51, and 53-71 are pending in the application.

The Examiner objected to claims 16, 34-36, 40, 44, and 46-54 due to enumerated informalities. Absent claims 34-36 and 52, which have been cancelled, the claims have been amended to correct those informalities.

Claim Rejections - 35 U.S.C. §102

The Examiner rejected claims 1-3, 5-6, 8-10, 12-20, 22-24, 26-27, and 29-36 under 35 U.S.C. §102(b) as being anticipated by US Patent No. 6,132,448 to Perez et al. (hereinafter 'Perez'). As claims 8 and 20-36 have been cancelled, discussion will be limited to claims 1-3, 5-6, 9-10, and 12-19.

As amended, claim 1 recites a minimally invasive apparatus for harvesting, *inter alia*, bone marrow cells. The apparatus comprises a rigid cannula having a proximal end and a distal end with an opening, said distal end including a cutting tip that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells. The apparatus further comprises a sheath disposed co-axially about a portion of the cannula for providing and maintaining a single percutaneous puncture site. It is respectfully submitted that Perez does teach or suggest the subject matter of claim 1, as amended. Specifically, Perez does not teach or suggest a sheath disposed co-axially about a portion of the cannula for providing and maintaining a single percutaneous puncture site.

The Examiner suggests that Perez teaches this sheath (See Office Action Pg. 4, at the discussion of claim 8). However, Perez teaches an outer member 11 that has a plastic housing hub 16 unremovably secured to the proximal end so as to be a permanent part of the outer member 11 (Col. 2, lines 39-41; Fig. 3). The current invention utilizes a rigid tubular sheath 100 that is disposed co-axially about a portion of the main body portion 66 of the cannula 60 (Pg. 18, lines 3-4). The inner surface 112 of sheath 100 is dimensioned to fit tightly over the outer surface 74 of the cannula 60 but allow relative movement between the cannula 60 and the sheath 100 (Pg. 18, lines 9-13). An obturator 150 is inserted into the sheath 100 and subsequently penetrates the skin near the iliac crest 152. Once this penetration has been achieved, the obturator 150 is withdrawn from the sheath 100, which remains in a percutaneous position to form a percutaneous access passage for receiving the cannula 60 of the apparatus 20 to begin cutting into the iliac crest 152 (Pg. 20, line 19 - Pg. 21, line 4; Figs. 1, 2, and 4). As the housing hub 16 is unremovably secured to the outer member 11, it cannot possibly (a) allow relative movement between the hub 16 and the member 11 or (b) act as a percutaneous access passage. Therefore, because Perez does not teach or suggest the subject matter of claim 1, as amended, it is respectfully submitted that claim 1, as amended, is allowable.

Claims 2-7 and 9-19 depend from claim 1 and are allowable for at least the same reasons as claim 1. Additionally, claims 2-7 and 9-19 are allowable for the specific limitations of each claim.

The Examiner rejected claims 1-5 & 7 under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,575,293 to Miller et al. (hereinafter 'Miller'). It is respectfully submitted that claim 1, as amended, patentably defines over Miller, and is therefore allowable.

Claim 1, as amended, substantially incorporates the subject matter of cancelled claim 8, which recites a sheath disposed co-axially about a portion of the cannula for providing and maintaining a single percutaneous puncture site. Miller does not teach or suggest a sheath disposed co-axially about a portion of the cannula. Therefore, it is respectfully submitted that claim 1, as amended, patentably defines over Miller, and is thus allowable.

The Examiner also rejected claims 37, 39, 42 & 44 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application No. 2003/0055373 to Sramek et al. (hereinafter 'Sramek'). It is respectfully submitted that claim 37, as amended, patentably defines over Sramek, and is therefore allowable.

As amended, claim 37 substantially incorporates the subject matter of cancelled claim 38, which recites the step of supplying irrigation fluid to the distal end of cannula to minimize thermal or mechanical trauma to the harvested cells and to help carry the harvested bone marrow cells, blood, and bone fragments into the passage. Sramek does not teach or suggest supplying irrigation fluid to the distal end of the cannula. Therefore, it is respectfully submitted that claim 37, as amended, patentably defines over Sramek, and is thus allowable.

Claims 39, 42 & 44 depend from claim 37 and are allowable for at least the same reasons as claim 37. Additionally, claims 39, 42 & 44 are allowable for the specific limitations of each claim.

The Examiner also rejected claims 46, 51, and 53 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application No. 2002/0042581 to Cervi (hereinafter 'Cervi'). It is respectfully submitted that claim 46, as amended, patentably defines over Cervi, and is therefore allowable.

As amended, claim 46 substantially incorporates the subject matter of cancelled claim 52, which recites the steps of providing a sheath that is disposed co-axially about a portion of the cannula and inserting the sheath percutaneously to the cortex of the bone so that the sheath provides and maintains a single percutaneous puncture site for harvesting bone marrow cells, blood, and bone fragments. Cervi does not teach or suggest providing a sheath disposed co-axially about the cannula for maintaining a percutaneous puncture site. Therefore, it is respectfully submitted that claim 46, as amended, patentably defines over Cervi, and is thus allowable.

Claims 51 and 53 depend from claim 46 and are allowable for at least the same reasons as claim 46. Additionally, claims 51 and 53 are allowable for the specific limitations of each claim.

The Examiner also rejected claims 46-51 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,913,859 to Shapira (hereinafter 'Shapira'). It is respectfully submitted that claim 46, as amended, patentably defines over Shapira, and is therefore allowable.

As amended, claim 46 substantially incorporates the subject matter of cancelled claim 52, which recites the steps of providing a sheath that is disposed co-axially about a portion of the cannula and inserting the sheath percutaneously to the cortex of the bone so that the sheath provides and maintains a single percutaneous puncture site for harvesting bone marrow cells, blood, and bone fragments. Shapira does not teach or suggest providing a sheath disposed co-axially about the cannula for maintaining a percutaneous puncture site. Therefore, it is respectfully submitted that claim 46, as amended, patentably defines over Shapira, and is thus allowable.

Claims 47-51 depend from claim 46 and are allowable for at least the same reasons as claim 46. Additionally, claims 47-51 are allowable for the specific limitations of each claim.

Claim Rejections - 35 U.S.C. §103

The Examiner rejected claim 11 under 35 U.S.C. §103(a) as being unpatentable over Perez in view of Miller. As discussed supra, claim 1, as amended, is allowable. Claim 11 depends from claim 1 and is allowable for at least the same reasons as claim 1. Additionally, claim 11 is allowable for its specific limitations.

The Examiner rejected claim 40 and 41 under 35 U.S.C. §103(a) as being unpatentable over Sramek in view of Shapira. As discussed supra, claim 37, as amended, is allowable. Claims 40 and 41 depends from claim 37 and are allowable for at least the same reasons as claim 40. Additionally, claims 40 and 41 are allowable for the specific limitations of each claim.

The Examiner rejected claim 43 under 35 U.S.C. §103(a) as being unpatentable over Sramek in view of US Patent No. 4,744,364 to Kensey (hereinafter 'Kensey'). As discussed supra, claim 37, as amended, is allowable. Claim 43 depends from claim 37 and is allowable for at least the same reasons as claim 37. Additionally, claim 43 is allowable for its specific limitations.

The Examiner rejected claim 45 under 35 U.S.C. §103(a) as being unpatentable over Sramek in view of Perez. As discussed supra, claim 37, as amended, is allowable. Claim 45 depends from claim 37 and is allowable for at least the same reasons as claim 37. Additionally, claim 37 is allowable for its specific limitations.

The Examiner rejected claim under 54 U.S.C. §103(a) as being unpatentable over Shapira in view of Perez. As discussed supra, claim 46, as amended, is allowable. Claim 54

depends from claim 46 and is allowable for at least the same reasons as claim 46.

Additionally, claim 46 is allowable for its specific limitations.

New Claims

New claim 55 has been added to more particularly point out and define the current invention. New claim 55 recites a minimally invasive apparatus for harvesting, *inter alia*, bone marrow cells. The apparatus comprises a rigid cannula having a proximal end and a distal end with an opening, the distal end including a cutting tip that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells. The cannula further includes an inner surface defining an internal passage that extends from the opening toward the proximal end. The apparatus further comprises: means for applying suction to the internal passage in the cannula for drawing bone marrow cells from the bone tissue by said cutting tip into the internal passage for collection, means for controllably supplying irrigation fluid into the internal passage in the cannula, and means for controllably injecting an anticoagulant fluid into the harvested bone marrow cells during collection. It is respectfully submitted that the subject matter of new claim 55 patentably defines over existing art.

Miller teaches a tissue collecting and staging device 10 that includes an irrigation fluid source 208, a vacuum source 216, a collection container 28 for storing the acquired tissue, and channel 23 that removed tissue travels through to get from the cutting tool 202 to container 28 (Col. 5, lines 26-28).

Likewise, Perez teaches a cutting assembly 10 that includes a cutting tool 24, irrigation liquid that is supplied to passageway 19 (Col. 3, lines 39-40), and a suction source that is connected with passageway 42 (Col. 4, lines 1-5). However, neither device teaches or

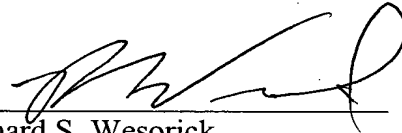
suggests having further means for controllably injecting an anticoagulant fluid into harvested bone marrow cells. The present invention provides a source 130 of anticoagulant fluid that is fluidly connected to suction 126 so that the anticoagulant fluid can be injected into the harvested bone tissue as it is drawn through the suction line and into the collection reservoir 120 (Pg. 19, lines 12-16), which helps to decrease the mobility of the harvested bone marrow tissue. The collected tissue in the Miller device passes from the cutting end 206, through cannula 204 and aspiration line 214, and into collection container 28. Therefore, Miller does not teach or suggest injecting an anticoagulant fluid into harvested bone marrow cells during collection. Furthermore, although the device in Perez has a passageway 19 for allowing irrigation liquid to reach cutting tool 24, there is no suggestion that the passageway 19 is used for the harvesting and collection of bone marrow. Thus, Perez cannot teach or suggest means for controllably injecting anticoagulant fluid into harvested bone marrow cells during collection. Therefore, it is respectfully submitted that new claim 55 is patentable in view of existing art.

New claims 56-71 depend from claim 55 and are allowable for at least the same reasons as claim 55. Additionally, claims 56-71 are allowable for the specific limitations of each claim.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the above-identified application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



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